Section: Biochemistry

Original Research Article

"ANALYSIS OF CRITICAL ALERT VALUES IN CLINICAL BIOCHEMISTRY LABORATORY AT A TERTIARY CARE HOSPITAL"- A CROSS SECTIONAL STUDY

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Abstract

Background: The idea of critical alert value can be understood as an expected unsafe lab result requiring prompt physician's notice and intervention for reducing morbidity or mortality of patient. It has been broadly embraced as a norm of good Laboratory practice and a mandatory requirement of "NABL". This practice improves clinical outcome, patient safety and operational efficiency of large and busy hospitals. **Aim & Objectives:** We performed this study to evaluate the scenario of our laboratory for the notification of critical values and to assess the strengths and weaknesses of our performance. **Material & Methods:** In NABL accreditated laboratory, we analyzed critical value alert logbook and reporting practices of 01 year. Statistical analysis was done using Microsoft Office Excel software and SYSTAT version 13.2. **Result:** The Study revealed that, in clinical biochemistry laboratory total 397675 tests were analyzed in study duration. Out of which 2.3% (9197) values were critical value alert. The maximum critical alert call back was for serum urea (18%) and serum creatinine (17.7%). In electrolytes, maximum alert recorded were for potassium (9.4%) followed by sodium (7.6%). Minimum call back was for CSF glucose & protein (0.1%), though samples received were also low. We found highest (36.5%) alerts were for patients in wards & ICU followed by emergency and trauma centre patients (32.8%) and 30.7% for our hospital OPD patients. Notification time to patient or treating physician was found from 10 to 30 minutes. **Conclusion:** On evaluation of critical values alert system in our health centre it was in accordance with that reported in the literature.

INTRODUCTION

The concept of critical value in patient care is well recognized and highly discussed issue in present era among health care providers, most of reputed hospitals and laboratories embrace it as quality indicator of good clinical practice. Some healthcare providers also term this as Panic value or alert. About three decades back, Lundberg defined it as a laboratory result that suggests the patient is in imminent danger unless appropriate therapy is initiated promptly.[1] The idea of critical alert value can be understood as an expected unsafe lab result requiring prompt physician's notice and intervention for reducing morbidity or mortality of patient.

Critical or Panic alert is not limited up to ICU or Emergency care of patients but plays a very important role in OPD/IPD and day carepatients.Now days many employer have a provision of periodic health checkups for their staff, and general population is also having more awareness for self-motivated heath checkups. All these Individuals are highly benefitted in terms of seeking prompt medical care if they get a critical or panic alert regarding their investigation on routine health checkup from Laboratory.

The laboratory accrediting agencies like NABL, CAP, CLSI, have included critical value reporting as a mandatory requirement for accreditation of Laboratory.[2,3] Moreover, the immediate notification of a critical value as a special requisite has been recognized and implemented worldwide through the International Organization for Standardization (ISO) 15189:2012, and has been

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adopted as a standard of Good Laboratory Practice.[4,5]

On the basis of available literature we concluded that there is no accord on the list of analytes which should be considered for critical values alerts. Cut off limits for critical value also differs as per age, gender and Laboratory protocols. For the sake of standardization in health care, physicians and laboratory doctors must make an agreement on the biomarkers and the critical value cut off limits of each anaytes, which should be established by each laboratory as per their requirements.[6-9] Many organizations like ISO:15189:2012, British Royal College of Pathologist have issued guidelines for the reporting of critical results but those guidelines also doesn't cover all aspects of Critical alert.[10] Furthermore, separate lists are required for different study groups , as critical values will differ between genders, neonatal, paediatric, geriatric and adult patients.[11] Panic values are generally identified in the laboratory by Laboratory Doctor or technician involved in analysis of sample. It is essential to confirm the validity of critical values from the beginning to make sure that there are no pre or analytical errors which can lead to false results and affect the patient treatment.[12] Whenever a critical value has been validated, it is necessary to inform the treating doctor or nurse and if possible to patient also.

Critical value reporting procedures must be considered as a vital laboratory outcome measurement because they are a sign of clinical effectiveness, patient safety and operational efficiency of large and busy Laboratories and hospitals. To make the critical value reporting protocols effective and quick, the Laboratories as well hospitals may focus on the key requirements involved in the process. These types of studies are few which have been reported in the literature.

In our country healthcare services have very wide network in both government and private sectors. The information being reported pertaining to the critical alert reporting systems in various setups is very limited. It is very important to have nationwide information and data regarding the procedures and their effectiveness for the panic alert reporting in different setups.

We performed this study to evaluate the scenario of our hospital laboratory which is "NABL" accreditated, for the notification of critical values and to assess the strengths and weaknesses of our system.

MATERIALS AND METHODS

All medical, surgical specialties and super specialities are available in the hospital for outpatient consultation and admission facilities along with 24x7 functional emergency and trauma centre. As an essential part of hospital, our Laboratory services are also available round the clock. In study period from August 2018to July 2019, the Biochemistry laboratory performed 397675 reportable tests, of which 33% for OPD, 31% for emergency and trauma(ED) and 36% were for admitted patients (IPD). [Table 1]

We conducted this cross-sectional study at NABL accreditated Central Laboratory biochemistry section of our tertiary Care Hospital in national capital region. We collected data from critical value alert logbook for reporting practices of 01 year from Aug 2018 to July 2019 which was analyzed in detail. We performed the study with aim "to evaluate the scenario of our laboratory for the notification of critical values as a way to act upon strengths and weaknesses of our overall performance".

Critical Results Reporting Protocols: Our Laboratory has enlisted the analytes for critical alert as per requisite of treating doctors from various specialties for patient care. This list is revised every year with detailed discussion with clinicians as per the changing modalities in patient care. Biochemistry critical call back list for study duration comprised of the analytes as per [Table 2].

Authorized personnel in laboratory staff are responsible for ensuring critical results are reported according to procedure. On identifying the critical value, the senior laboratory technician should recheck the critical result for all quality control parameters to exclude any procedural error. All critical results should be reported to health care provider i.e. treating doctor or nurse immediately and to patient also if possible on phone. All alerts sent for critical value, will be documented in a designated logbook simultaneously under heading of:-

- The analyte name, critical result value with all patient details, date and time. The reporting and verification of "read back" of these values to the appropriate health care provider.
- Full name and designation of the laboratory individual reporting the critical results.
- Full name and designation of the health care provider who was informed of the critical results with date and time.
- Any difficulty, including refusal to accept the results, that may be encountered in notifying in a timely manner should be noted. After the call the laboratory's report will be printed, signed by authorized personnel and sent to dispatch section.
- Logbook will be daily checked and signed by Laboratory in charge

Statistical analysis: We verified the record for reported analyte, time of reporting an alert after generation of result, mode of communication, to whom it was reported, Status of patient i.e. Emergency dept, OPD, IPD, month wise alerts and difficulty or shortcomings encountered during the procedure. The data obtained for different criteria was evaluated using descriptive statistical analysis.

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Statistical analysis was done using Microsoft Office Excel software and SYSTAT version 13.2.

RESULTS

The Study revealed that, in clinical biochemistry laboratory total 397675 tests were analyzed in study duration from August 2018 to July 2019(Table 1). Out of which 2.3% (9197) values were identified to be meeting or exceeding the cut off for critical value alert (Graph -1).The maximum critical alert call backs among all the analytes for which Biochemistry section follows the call back protocol was for serum urea 18 %(1663/9197) and serum creatinine 17.7 %(1634/9197).In electrolytes, maximum alert recorded were for potassium 9.4% (873/9197) followed by sodium 7.6 %(701/9197).Minimum call back was for CSF glucose & protein 0.1 % each (18/9197), though CSF samples received were also very low. We also analysed the month wise trends in critical alerts during our study period and found that maximum were in month of October and February, while lowest were in month of September and April. This monthly trend was also in consensus or directly proportional to the number of patients registered and admitted in various departments in respective months. We found highest (36.5%) alerts were for patients in wards & ICU and most of them were admitted in Nephrology & Dialysis unit of our hospital followed by emergency and trauma centre patients (32.8%) and 30.7% for our hospital OPD patients(Graph-4). In this study, we also checked for difficulties faced by Laboratory staff in the procedure of call back and found that most of the delays were due to busy phone lines of wards & ICU. Most of the time patients or their attendants were not aware of correct patient's diagnosis, requested investigations details and registration identification .Despite all these hurdles our Laboratory staffs was successful in maintain notification time to patient or treating physician/nurse ranging from 10 to 30 minutes (Table-3).

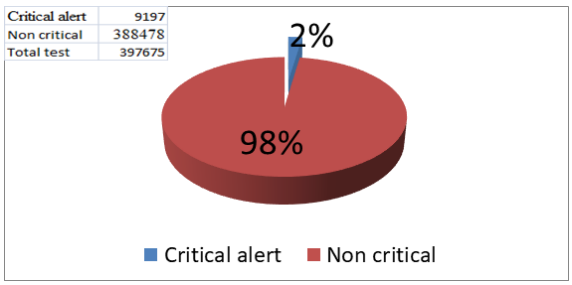

Figure 1: Indicate Total critical alerts notified in study

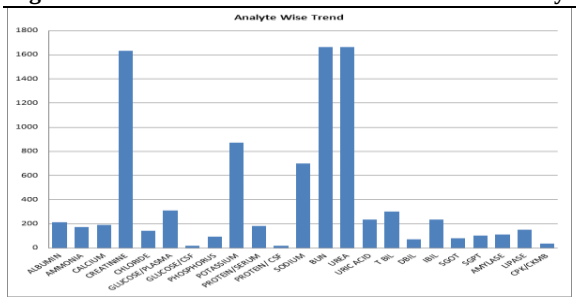

Figure 2: Indicates analyte wise critical alert trends in Laboratory

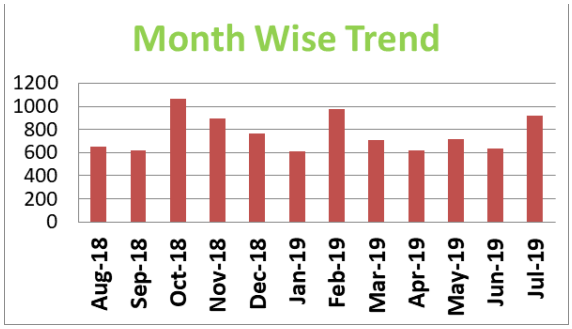

Figure 3: Indicates Month wise trends of critical alert in study duration

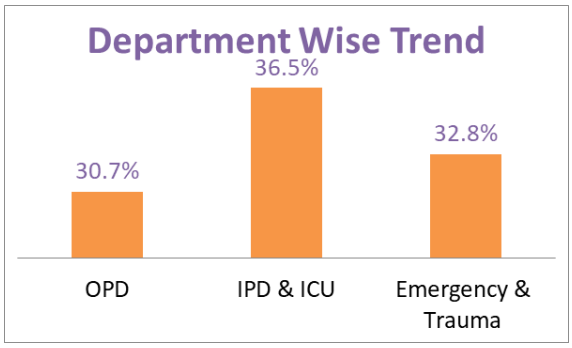

Figure 4: Indicates Registration department wise trends of critical Alert

Table 1: Total Investigations performed in study duration in Clinical Biochemistry Laboratory

Total Investigation Count	Out Patient Department	Inpatient Department	Emergency & Trauma centre	Total
Total	130477(33%)	145093(36%)	122105(31%)	397675

Table 2: Critical Alert scope for study duration

S. No.	Analyte	Age Group	Critical Alerts		Units
			Low	High	
1.	Serum Albumin	Children	1.7	6.8	g/dL
2.	Serum Ammonia	Children	-	109	µmol/L
3.	Serum Bilirubin	New Born	-	15	mg/dL
		Adult	-	15	mg/dL
4.	Serum Calcium	Children	6.5	12.7	mg/dL
		Adult	6	13	mg/dL

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5.	Serum Creatinine	Children	-	3.8	mg/dL
		Adult	-	4.0	mg/dL
6.	Serum Chloride	Adult	80	120	mmol/L
7.	Glucose (Plasma)	New Born	30	325	mg/dL
		Children	46	445	mg/dL
		Adult	40	450	mg/dL
	Glucose (CSF)	Children	31	-	mg/dL
		Adult	40	200	mg/dL
8.	Serum Phosphorus	Adult	1	8.9	mg/dL
9.	Serum Potassium	New Born	2.8	7.8	mmol/L
		Adult	2.8	6.2	mmol/L
10.	Protein (Serum)	Children	3.4	9.5	g/dL
	Protein (CSF)	Children	-	188	mg/dL
11.	Serum Sodium	Adult	120	160	mmol/L
12.	Serum BUN	Children	-	55	mg/dL
		Adult	-	80	mg/dL
13.	Serum Urea	Children	-	118	mg/dL
		Adult	-	170	mg/dL
14.	Serum Uric Acid	Children	-	12	mg/dL
		Adult	-	13	mg/dL

Table 3: Time taken in notification of critical alerts to respective department.

Department	(Reporting Time) (Minutes)		
	Minimum	Maximum	Mean
IPD and ICU	10	30	20
OPD	30	50	40
Emergency & Trauma Centre	10	30	20

DISCUSSION

In our study, we observed a wide-ranging analysis of the critical value call back reporting procedure of a tertiary care hospital in national capital region. Study comprised the information of the scope, volume, timing and functional aspects of critical value reporting. Parameters included are of practical importance and also related to quality indicators of health care setups. This analysis provides a perspective for self-evaluation and process upgrading.

Though call back protocols increases workload and responsibility of Laboratory staff but it is important to attain efficient use of clinical laboratory to maximize clinical benefits for both patient and treating doctor. If addition of analytes to the critical callback lists without proper discussion and clinical utility which does not meet the norm of the "requiring prompt physician's notice and intervention" standards may deteriorate the importance of a critical value and lead to needless calls for clinicians and Patients. In addition to this, there are many clinical treatment stages like chemotherapy in malignancy in which the "critical" test value is detected and reporting of these results will not affect the patient treatment and care guidelines. Intimation of this type of alerts by phone by Lab staff is a burden in terms of the resources required to convey the alert and complete the full documentation.

In pretext of all these technical hitches, it is mandatory to limit the number of phone calls by careful revision of the critical values analyte scope. During the revision of scope, analytes which need to be incorporated in the critical values list or considered to be deleted, vital policy is to inspect the consequences of critical value reporting for each analyte in improving the prognosis of patient. These requirements must be considered with consultation of clinicians and laboratory management.

Single changes in critical value reporting list will lead to adding or minimizing of thousands of phone calls by the lab personnel and avoidable documentation. Patients coming to hospital OPD for their illness or routine check-up and critical values in their investigations pose different type of challenges to laboratory staff. For timely reporting of their alerts to responsible clinicians or patient themselves availability of clinician, phone coverage, and educational status of patient plays a significant role. The time required for outpatient specimen transport to lab and processing in scheduled batches often lead to report generation in the evening when the outpatient clinic or physician's office is closed. One of the common causes of late intimation of critical alerts was limited access to phone of patient. Like admitted patients, there is no fixed patient location or responsible individual who can be contacted for the purpose. Another issue we recognized as causing delay for outpatients was unreadable or non-availability of correct patient information. For the Improvement of facility for outpatients, we suggested to registration staff to obtain alternate details of responsible person whom laboratory or hospital can contact in case of urgency. Strengthening of communication between the laboratories and the outpatient care centre was also recommended.

The potential for technological solutions to improve the process of critical value reporting is evident in numerous reports.[13,14] The application of information technology and artificial intelligence to mechanically communicate with the responsible

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person has been established in reducing the critical value reporting time in conducted trials and testing in developed countries. Efficient and smooth functioning of automated critical value reporting, interfaces from the LIS to technologies that facilitate bidirectional communication (such as SMS, e-mail, personalized social media platforms) need to be developed and implemented.

Inclusion of Artificial intelligence in the LIS system can empower the Laboratory for automatically reporting system with reliability and verify the identity of the responsible person for further communication. In large and busy setups, this routine job becomes more difficult because there are different coverage lists, tests ordered by specialists, not acknowledged to the ward doctors and shifting of patients for referrals to different specialities. Most of the time duty doctors and nurses are busy in patient care and procedures and they are not quickly available to take call on designated phone numbers of Emergency department, general wards and ICU units.

An automatic reporting system in case could go wrong and cause risky delays in intimation if not properly implemented. The system must have an "acknowledgment" function such that the laboratory can ensure that the responsible caregiver received the result.[15] Automatic systems application also needs an intensification system so that non-confirmation or no acknowledgment of the critical result could switch to another mechanism for contact.

The development of alert reporting software should allow highly significant approaches to critical value reporting. Rules-based logic can be applied to laboratory values to build alerts that take into account not only the result value, but also other related results, a change in the current test result from previous results and other parameters to personalize the alert to the patient. The ability to provide a specialist specific critical values list could eliminate a lot of unnecessary critical value calls. When interfaced with automated alerting systems, these systems have the potential to improve patient safety and provide more context-sensitive critical value reporting. The practical implementation of this scenario would be constrained by regulations that require all critical results to be communicated.

We found our study findings comparable with studies Arbiol-Roca A. et al.(Spain),[16] Anand S. Dighe . et al.(Boston, U.S.A),[17]Dagan Yang et al.(China),[18] K.N. Desai et al.(India) (19). On going through the guidelines for the reporting of critical results issued by: ISO-15189:2012,British Royal College of Pathologists, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), United States and College of American Pathologists. All current guidelines states that, the laboratory is required to have a self defined written policy and documentation system for critical values alerts reporting system.

CONCLUSION

The evaluation of critical values alert system in our health care centre was found at par according to that reported in the literature. It is obligatory for each laboratory to have a policy and protocol on how to manage critical values alert in maximum patient welfare. Use of information technology to automatically communicate alert via SMS, e-mail, personalised social media platforms, with interface from the LIS need to be developed and used. The system needs to have an "acknowledgment" function and Periodical reviews and audits with larger time duration and data are recommended.

REFERENCES

1. Lundberg GD. When to panic over abnormal values. Med Lab Obs 1972;4:47-54.
2. College of American Pathologists. Laboratory Accreditation checklist. Available at: http://www.cap.org/apps/cap.por- .
3. Joint Commission on Accreditation of Healthcare Organizations. International Patient Safety Goals 2007. Available at: http://www.jointcommission.org/ PatientSafety/National-PatientSafetyGoals.
4. International Organization for Standardization (ISO). ISO15189:2012. Medical laboratories particular requirements for quality and competence. Geneva, Switzerland: Internati-onal Organization for Standardization; 2012.
5. Clinical and Laboratory Standards Institute (CLSI).Management of Criticaland Significant-Risk Result. CLSI guidelineGP47 1st Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2015
6. Kost GJ. Critical limits for emergency clinician notification at United States children's hospitals. Paediatrics 1991;88:597-603.
7. Kost GJ. Critical limits for urgent clinician notification at US medical centers. JAMA. 1990;263:704-7. https://doi.org/10.1001/ jama.1990.03440050098042
8. Fine RH. Laboratory critical limits. JAMA. 1990;264:334. https://doi.org/10.1001/ jama.1990.03450030050019
9. Lundberg GD, Iverson C, Radulescu G. Now read this: the SI units are here. JAMA. 1986;255:2329-39. https://doi.org/10.1001/ jama.1986.03370170093043
10. Croal B. The communication of critical and unexpected pathology results. The Royal College of Pathologists. Available at: https://www.rcpath.org/resourceLibrary/the-communication
11. Lippi G, Mattiuzzi C. Critical laboratory values communication: summary recommendations from available guidelines. Ann Transl Med. 2016;4:400. https://doi.org/10.21037/ atm.
12. Agarwal R, Chhillar N, Tripathi CB. Study of variables affecting critical value notification in a laboratory catering to tertiary care hospital. Indian J.Clin Biochem. 2015;30:89-93. https://doi.org/10.1007/s12291 013-0409-x
13. Bates DW, Pappius E, Kuperman GJ, Sittig D, Burstin H,Fairchild D et al. Using information systems to measure and improve quality. Int J Med Inform 1999;53:115-124.
14. Tate KE, Gardner RM, Weaver LK. A computerized laboratory alerting system. MD Comput 1990;7:296-301.
15. Dighe AS, Rao A, Coakley AB, Lewandrowski KB. Analysis of laboratory critical value reporting at a large academic medical center. AM J Clin Pathol 2006;125:758-764.
16. Arbiol-roca A, Cano-corres R, Dastis-arias M, Dot-bach D. Special issue : Original articles Responsible writing in science. 2019;29(11):1–7.
17. Dighe AS, Rao A, Coakley AB, Lewandrowski KB. Analysis of Laboratory CriticalValue Reporting at a Large Academic Medical Center. 2006;758–64.
18. Yang D, Zhou Y, Yang C. Analysis of Laboratory Repeat Critical Values at a Large Tertiary Teaching Hospital in China. 2013;8(3):11–4.
19. Desai KN, Chaudhari S. Analysis of Critical values in NABL (National Accreditation Board for Testing and Calibration Laboratories) accredited Hematology and Clinical Pathology laboratory . 2017;6–10.

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